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The Role of Magnetic Resonance Imaging in Predicting Pathological Complete Response in Breast Cancer Patients Receiving Neoadjuvant Chemotherapy

Noeadjuvan Kemoterapi Alan Meme Kanseri Hastalarında Patolojik Tam Yanıtı Tahmin Etmede Manyetik Rezonans Görüntülemenin Rolü

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Abstract

Objective: Neoadjuvant chemotherapy (NACT) has been used more frequently in the treatment of non-metastatic breast cancer. Achieving a pathological complete response (pCR) after NACT provides us with information about the prognosis of the disease. We aimed to investigate the diagnostic accuracy of preoperative magnetic resonance imaging (MRI) in predicting pCR in patients with breast cancer.

Method: The charts of patients who received NACT for breast cancer between 2018 and 2024 were retrospectively analyzed. Factors associated with radiologic complete response (rCR) and pCR were analyzed in univariate and multivariate settings. The correlation between rCR and pCR according to MRI interpretation was analyzed.

Results: A total of 153 patients were included in this study; 26 (17%) of these patients achieved rCR, and 39 (25.5%) achieved pCR. A statistically significant correlation was found between pCR and rCR assessed on MRI. Sensitivity, specificity, accuracy, pCR predictive value (PPV) and non-pCR predictive value were estimated at 51.3%, 94.7%, 83.7%, 76.9% and 85%, respectively. Statistically significant correlations between rCR and pCR were found in Luminal A ($p<0.05$), Luminal B ($p<0.05$), HER2-positive ($p<0.05$), but not in triple negative subtypes ($p>0.05$). In univariate and multivariate analysis, tumor characteristics significantly associated with both rCR and pCR were tumor size, lymph node metastasis and molecular subtypes.

Öz

Amaç: Neoadjuvan kemoterapi (NACT), metastatik olmayan meme kanserinin tedavisinde daha sık kullanılmaktadır. NACT sonrasında patolojik tam yanıt (pCR) elde etmek, bize hastalığın prognozu hakkında bilgi sağlar. Meme kanseri hastalarında pCR'yi tahmin etmede preoperatif manyetik rezonans görüntülemenin (MRI) tanısal doğruluğunu araştırmayı amaçladık.

Yöntem: 2018-2024 yılları arasında meme kanseri nedeniyle NACT alan hastaların çizelgeleri retrospektif olarak analiz edildi. Radyolojik tam yanıt (rCR) ve pCR ile ilişkili faktörler tek değişkenli ve çok değişkenli ortamlarda analiz edildi. MRI yorumlamasına göre rCR ve pCR arasındaki korelasyon analiz edildi.

Bulgular: Bu çalışmaya toplam 153 hasta dahil edildi; bu hastaların 26'sı (%17) rCR'ye ulaşırken, 39'u (%25,5) pCR'ye ulaştı. pCR ve MRI'da değerlendirilen rCR arasında istatistiksel olarak anlamlı bir korelasyon bulundu. Duyarlılık, özgüllük, doğruluk, pCR öngörü değeri (PPV) ve pCR dışı öngörü değeri sırasıyla %51,3, %94,7, %83,7, %76,9 ve %85 olarak tahmin edildi. rCR ve pCR arasında istatistiksel olarak anlamlı korelasyonlar Luminal A'da ($p<0,05$), Luminal B'de ($p<0,05$), HER2 pozitif ($p<0,05$) bulundu, ancak üçlü negatif alt tiplerde ($p>0,05$) bulunmadı. Tek değişkenli ve çok değişkenli analizde, hem rCR hem de pCR ile önemli ölçüde ilişkili tümör özellikleri tümör boyutu, lenf nodu metastazı ve moleküler alt tiplerdi.

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Abstract

Conclusion: MRI evaluation varies according to the subtype and after NACT showed a correlation between rCR and pCR.

Keywords: Breast cancer, magnetic resonance imaging, neoadjuvant chemotherapy, pathologic complete response, radiologic complete response

Öz

Sonuç: MRI değerlendirmesi alt tipe göre değişir ve NACT'den sonra rCR ve pCR arasında bir korelasyon gösterdi.

Anahtar kelimeler: Manyetik rezonans görüntüleme, meme kanseri, neoadjuvan kemoterapi, patolojik tam yanıt, radyolojik tam yanıt

Introduction

Breast cancer remains the most commonly diagnosed type of cancer worldwide (1). Traditional treatment methods (surgery + adjuvant chemotherapy) have an important place in the treatment approach, but neoadjuvant chemotherapy (NACT) is increasingly discussed and implemented in current breast cancer treatment guidelines.

NACT refers to systemic chemotherapy administered prior to planned surgery for patients with locally advanced breast cancer. Its primary goal is to transform initially inoperable tumors into operable ones, thereby offering patients the chance for surgical intervention and improving breast conservation rates. Additionally, NACT enables early assessment of the chemotherapy's impact on cancer tissue, which helps guide the selection of the most effective chemotherapy agents for the patient's future treatment (2).

When the data, in the literature, are examined, it has been observed that high pathological complete response (pCR) rates are achieved, when effective targeted therapies and chemotherapeutic agents are preferred in first-line treatment (3,4).

Currently, no standardized methods or imaging biomarkers are available in clinical practice to accurately predict pCR after NACT. Magnetic resonance imaging (MRI) is considered the most sensitive imaging modality that can be used to assess treatment response in patients undergoing NACT (5).

Radiomics is a feature extraction and analysis method commonly used in medical imaging. Radiomics analyzes pixel values in medical images and inter-pixel relationships.

It is thought that the application of radiomics techniques to magnetic resonance (MR) imaging will contribute positively to all stages of breast cancer with the additional data it will provide to the diagnosis, treatment and prognosis processes of breast cancer (6).

Scientific studies suggest that patients with radiologic complete response (rCR) show significant correlation with pCR (7).

Nevertheless, there is a limited number of studies investigating the relationship between rCR and pCR across various molecular subtypes, particularly where the Ki-67% proliferation index is used as a criterion.

In this study, we aimed to evaluate the effectiveness of post-treatment breast MRI in forecasting pCR following NACT using a large dataset from a single center.

Material and Methods

Patient Characteristics

We retrospectively analyzed breast MR imaging data of breast cancer patients with four or more cycles of NACT, at University of Health Sciences Turkey, İstanbul Training and Research Hospital between March 2018 and May 2024. The baseline data for our study were collected from the hospital's medical records database. We received approval from the University of Health Sciences Turkey, İstanbul Training and Research Hospital's Clinical Research Ethics Committee (date: 19.07.2024, number: 36).

The study included patients with histopathologically confirmed, radiologically non-metastatic breast cancer who had received NACT. Patients who underwent MRI to monitor tumor response to NACT and had at least two MRI evaluations was incorporated into the study. The initial MRI was conducted following the diagnosis and prior to NACT, and the second MRI was performed after completion of NACT, before surgery.

Patients who could not complete the NACT process had incomplete follow-up data were excluded. In Table 1, the baseline characteristics of the patients are displayed.

Most patients in the study received a combination of anthracycline and cyclophosphamide followed by taxane chemotherapy.

Along with these chemotherapeutic agents, HER2-positive breast cancer patients were also treated with targeted therapy using pertuzumab and trastuzumab. Some patients with triple-negative breast cancer received a carboplatin regimen combined with paclitaxel chemotherapy.

Pathological Classification

According to receptor positivity, tumors were categorized as estrogen receptor (ER) positive or progesterone receptor (PR) positive if the immunohistochemical (IHC) staining of the tumor tissue showed 1% or more positivity in tumor cell nuclei. The HER2 status (positive or negative) was assessed through IHC and/or fluorescence *in situ* hybridization (FISH) analysis of biopsy samples. In the IHC analysis, a score of 3+ was deemed positive, while scores of 0 to 1+ were considered negative. For tumors that received a 2+ score, further evaluation via FISH was conducted to check for *HER2* gene amplification.

The Ki-67% index was divided into three categories based on values: Less than 15%, between 15% and 40%, and more than 40%. Tumors were classified into molecular subtypes using IHC markers. The subtypes included Luminal A (ER-positive, PR ≥20%, HER2-negative, Ki-67% ≤15%), Luminal B (ER-positive, PR <20% or both ER and PR-positive, HER2-negative, or ER/PR/HER2-positive, with Ki-67% >15%), HER2-positive (ER and PR-negative, HER2-positive), and triple-negative (ER/PR/HER2-negative) groups. The Luminal B group was further divided into two subgroups based on the Ki-67% index: Those with Ki-67% <40% were classified as Luminal B low Ki-67%, while those with Ki-67% ≥40% were labeled as Luminal B high Ki-67%.

In postoperative pathology, the Miller-Payne grading system was utilized to assess the response to NACT. Grades 1 and 2 were classified as stable response; grades 3 and 4 as partial pathological response; and grade 5 as pCR. Residual ductal carcinoma *in situ* was excluded from the definition of pCR, irrespective of lymph node metastasis presence.

Table 1. Patient characteristics

		Min-max			Median	Avr. ± SD/n-%		
Age		**35.0**	**-**	**87.2**	**51.8**	**53.8**	**±**	**11.7**
Menopause	Premenopause					60		39.2%
	Postmenopause					93		60.8%
MR-T tumor size	T0					32		20.9%
	T1 (<2 cm)					41		26.8%
	T2 (2-5 cm)					39		25.5%
	T3 (>5 cm)					26		17.0%
	T4 (>5 cm)					15		9.8%
MR-N stage	N0					87		56.9%
	N1					44		28.8%
	N2					18		11.8%
	N2					1		0.7%
	N3					3		2.0%
Radiologic complete response	(-)					127		83.0%
	(+)					26		17.0%
Pathological tumor size	T0					42		27.5%
	T1 (<2 cm)					32		20.9%
	T2 (2-5 cm)					52		34.0%
	T3 (>5 cm)					21		13.7%
	T4 (>5 cm)					6		3.9%
PN-N stage	N0					67		43.8%
	N1					45		29.4%
	N2					22		14.4%
	N3					18		11.8%
Pathological complete response	(-)					114		74.5%
	(+)					39		25.5%

MR: Magnetic resonance, SD: Standard deviation

Breast MRI and Evaluation

MRIs were obtained using a 1.5 T MAGNETOM Aera device (Siemens, GERMANY). According to the breast MRI protocol, axial anterior contrast T1 with 3 mm slice thickness, axial STIR T2, sagittal T2 with 4 mm slice thickness for both breasts, and ADC maps and DWI b values (50-400-800 s/mm^2) were obtained. Dynamic sequences were acquired six times at 60-second intervals after contrast agent injection, and subtraction images were obtained from these sequences. Finally, a contrast fat-suppressed sagittal T1 VIBE sequence was obtained. MRI examinations were performed in a prone position using a breast coil. To minimize background contrast, patients were imaged between the tenth and fourteenth day of their menstrual cycle.

Statistical Analysis

SPS 28.0 software system was used for the analyses, and a p-value of less than p<0.05 was considered statistically significant. Statistics of the data included mean, maximum, minimum, median, ratio values, frequency, and standard deviation. The Shapiro-Wilk and Kolmogorov-Smirnov tests were used for assessing the distribution of variables. The Mann-Whitney U test was used to analyze independent quantitative data with abnormal distribution. The chi-square test was used for analyzing qualitative independent data, and if the chi-square test was not satisfied, Fischer's test was applied. Specificity, sensitivity and accuracy were calculated to evaluate the effectiveness of MRI after NACT. Multivariable regression was used to examine the simultaneous effects of multiple factors. The accuracy of MRI was measured using predictive values, including negative predictive value (NPV) and positive predictive value (PPV).

Results

The files of 570 patients who underwent NACT for breast cancer at the Oncology Clinic of University of Health Sciences Turkey, İstanbul Training and Research Hospital were analyzed. One hundred fifty-three patients with available MRI images and postoperative pathology results were included. Table 1 shows the baseline characteristics of the patients. The average age of the patients was 57.4±12.9 years, with 88.9% diagnosed with invasive ductal carcinoma. Among them, 22 patients (14.4%) were HER2-positive, 24 patients (15.7%) were triple-negative, and 107 patients (69.9%) were hormone receptor-positive.

Following NACT, all patients underwent surgery. The tumor diameter measured on pretreatment MRI was 4.26±1.95 cm (ranging from 1.5 to 10.6 cm), while the residual tumor diameter measured on post-NACT MRI was 2.41±1.31 cm (ranging from 0 to 6.5 cm).

Out of the cohort, 39 patients achieved pCR, and 26 patients had rCR, a statistically significant finding (p<0.05). The sensitivity, accuracy (ACC), specificity, PPV for pCR, and NPV were estimated to be 51.3%, 83.7%, 94.7%, 76.9%, and 85%, respectively (Table 2).

Additionally, we explored the correlation between rCR and pCR across different breast cancer subtypes. Statistically significant correlations between pCR and rCR were observed in the Luminal A, Luminal B, and HER2-positive groups, whereas no significant correlation was found in the triple-negative group.

Discussion

NACT plays a crucial role in managing locally advanced breast cancer. One study has clearly demonstrated that pCR achieved with NACT improves survival and is a key endpoint for improved prognosis (8). However, the definition of pCR continues to be debated, and there seems to be a lack of consensus in the literature, which complicates the objective comparison of results. In our study, we considered the lack of DCIS or malignant cells in the sections taken from the tumor site as pCR. In our study, we found that rCR rates and

Table 2. Comparison of breast MRI performance among tumor subtypes after NAC

Molecular subtype	Accuracy	Sensitivity	Positive PV	Specificity	Negative PV	p
All patients	83.7%	51.3%	76.9%	94.7%	85.0%	0.000
Luminal A	100.0%	100.0%	100.0%	100.0%	100.0%	0.025
Luminal B low Ki-67	93.3%	100.0%	50.0%	92.9%	100.0%	0.000
Luminal B high Ki-67	85.7%	25.0%	100.0%	100.0%	85.0%	0.003
HER 2 positive	68.2%	56.3%	100.0%	100.0%	46.2%	0.017
Triple negative	66.7%	40.0%	66.7%	85.7%	66.7%	0.151

MRI: Magnetic resonance imaging, NAC: Neoadjuvant chemotherapy

pCR rates were similar. We aimed to evaluate whether rCR had a significant relationship with pCR. We also wanted to determine the factors that may affect rCR and pCR.

From Table 3, we determined that tumor size measured by MRI after NACT was the most significant factor associated with both pCR and rCR. Other factors, including primary tumor size by MRI, nodal metastasis, and molecular subtype, were also significantly linked to pCR and rCR. This correlation may be attributed to the fact that smaller tumor size, earlier clinical classification, and higher proliferation rates are associated with a greater likelihood of response and a higher chance of achieving pCR and rCR post-NAC (9).

We also aimed to evaluate the precision of MRI in predicting pCR after NACT, particularly for each breast cancer subtype. We based our classifications on IHC markers used in both literature and clinical practice (10). Additionally, we categorized Luminal B breast cancer into two groups based on Ki-67% scores: Ki-67 >20% and Ki-67 <20%. Our findings indicated that rCR was significantly correlated with pCR, especially in the Luminal B, low and high Ki-67%, HER2-positive, and Luminal A subtypes. Nonetheless, we observed notable differences among these three groups.

Moreover, Luminal B, high Ki-67% and HER2-positive subtypes exhibited low NPV, but high PPV. This implies that residual lesions identified by MRI serve as reliable markers of non-pCR for these subtypes; however, the rCR diagnosed by MRI in these groups may be overestimated. Conversely, MRI predicted pCR in the triple-negative subtype with lower sensitivity, specificity, accuracy, PPV, and NPV, compared to the other subtypes, which is contrary to the findings reported in existing literature (11,12).

In our study, Luminal A and Luminal B breast cancers with low Ki-67% (<20%) were less likely to exhibit pCR or rCR following NACT . However, they achieved high specificity, sensitivity, ACC, NPV and PPV. These data were similar to the results of studies in the literature (13). Certainly, multicenter studies with a larger cohort of patients are needed to speak more precisely. However, MRI still demonstrated a good NPV for these two molecular subtypes. It indicates that the accuracy remains high if the MRI reveals a residual tumor. Some studies have shown that rCR assessed on MRI is not a clear marker for pCR (14,15). The biggest difference between our data and the data in these studies was that we applied the IHC classification methods recommended in the guidelines. We also set a more objective standard for evaluating rCR. rCR was described as the lack of DCIS and malignant cells. This may have contributed to the disparity between our study and the previously mentioned studies.

While pCR remains the gold standard for assessing pathology specimens after NACT, rCR can serve as a predictor of improved prognosis in clinical practice (16). However, there are challenges associated with diagnosing rCR following NACT. The treatment can induce reactive changes such as inflammation and fibrosis, which may result in non-specific contrast enhancement, leading to either underestimation or overestimation of tumor diameter on MRI (17).

Moreover, different molecular subtypes of breast cancer exhibit varying capabilities in achieving pCR. Ki-67%

Table 3. The correlation coefficient according to the clinical and tumor characteristics

Variables	rCR	pCR	rCR	pCR
	|R|	p-value	|R|	p-value
Age	0.043	0.45	0.032	0.584
Menopause (yes/no)	0.031	0.56	0.03	0.967
Primary tumor diameter by hand	0.02	0.006	0.024	0.011
Primary tumor diameter by MRI	0.025	<0.00	0.123	0.025
After NAC tumor diameter by MRI	0.32	<0.00	0.232	<0.00
Tumor grade	0.022	0.033	0.452	0.005
Clinical grade	0.143	0.027	0.167	0.02
Receptor status				
HR (positive/negative)	0.147	0.034	0.01	0.004
HER2 (positive/negative)	0.02	0.65	0.033	1.01
Ki-67% (low/medium/high)	0.32	0.23	0.287	0.004
Moleculer subtype	0.178	<0.00	0.02	<0.00

rCR: Radiologic complete response, MRI: Magnetic resonance imaging, NAC: Neoadjuvant chemotherapy, pCR: Pathological complete response

is a key marker for gauging response to neoadjuvant treatment, when Ki-67% exceeds 40%, the rate of pCR after NACT significantly increases, along with a higher rate of rCR diagnoses. In the Luminal B subtype, a Ki-67% ≥40% indicates a higher likelihood of achieving pCR, with rates comparable to those observed in HER2-positive breast cancer. Although the differences in molecular subtype did not significantly impact the diagnosis of rCR, high Ki-67% emerged as a strong predictor of rCR when compared to low Ki-67%.

Study Limitations

Our study has a number of limitations. The limitations are, firstly, a retrospective design and, secondly, a small sample size. As this was a single-center study, we aimed to employ consistent data analysis methods for both radiological and pathological evaluations.s Third, our study did not include immunotherapy agents the guidelines.

Conclusion

In conclusion, the precision of breast MRI in estimating pCR was high in patients receiving NACT for breast cancer. NPV, sensitivity, PPV and precision of MRI in predicting pCR differed significantly between molecular subtypes of breast cancer.

Ethics

Ethics Committee Approval: We received approval from the University of Health Sciences Turkey, İstanbul Training and Research Hospital's Clinical Research Ethics Committee (date: 19.07.2024, number: 36).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: İ.G., E.Ö., E.S.A., Ö.H., Concept: İ.G., B.G., M.B.U., Ç.U., R.U.G., Design: İ.G., B.G., E.S.A., Ç.U., R.U.G., Data Collection or Processing: İ.G., E.Ö., M.B.U., Analysis or Interpretation: İ.G., E.S.A., Ç.U., R.U.G., Literature Search: İ.G., E.Ö., M.B.U., Writing: İ.G., B.G., Ö.H.

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